UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHAMBERS OF
MADELINE COX ARLEO
UNITED STATES DISTRICT JUDGE

MARTIN LUTHER KING COURTHOUSE
50 WALNUT ST. ROOM 4066
NEWARK, NJ 07101
973-297-4903

July 31, 2020

VIA ECF

LETTER ORDER

Re: Amad Odeh, et al. v. Immunomedics, Inc., et al.,
Civil Action No. 18-17645

Dear Litigants:

This matter comes before the Court by way of Defendants Immunomedics, Inc.'s ("Immunomedics"), Behzad Aghazadeh's ("Aghazadeh"), Scott Canute's ("Canute"), Michael Garone's ("Garone"), Peter Barton Hutt's ("Hutt"), Khalid Islam's ("Islam"), Usama Malik's ("Malik"), Michael Pehl's ("Pehl"), and Morris Rosenberg's ("Rosenberg," and, with Aghazadeh, Canute, Garone, Hutt, Islam, Malik, and Pehl, the "Individual Defendants," and collectively with Immunomedics, "Defendants") Motion to Dismiss, ECF No. 48, Lead Plaintiffs Boris Saljanin's and the Construction Industry and Laborers Joint Pension Trust's (collectively, "Plaintiffs") Consolidated Complaint ("Consol. Compl."), ECF No. 41,[1] pursuant to Federal Rule of Civil Procedure 12(b)(6). Plaintiffs oppose the Motion. ECF No. 50. For the reasons explained below, the Motion is **DENIED**.

I. BACKGROUND

This matter is a putative class action for securities fraud arising out of Immunomedics' disclosures regarding the U.S. Food and Drug Administration ("FDA") inspection and approval process for a drug called IMMU-132. See generally Consol. Compl. Plaintiffs seek to represent "all persons or entities who purchased or otherwise acquired the common stock of Immunomedics . . . between February 9, 2018 and January 17, 2019, inclusive (the 'Class Period'), and were damaged thereby." Id. ¶ 1.

A. The Defendants

Immunomedics is a biopharmaceutical company that develops "monoclonal antibody-based products for the targeted treatment of cancer," and, as relevant here, focused on

[1] On September 9, 2019, the Court granted the motion to consolidate this case with No. 19-5151 and appoint Plaintiffs as lead plaintiffs. See ECF No. 34. Consistent with that Order, Plaintiffs filed the Consolidated Complaint on November 18, 2019, see ECF No. 41, and the instant Motion followed, see ECF No. 48.

commercializing IMMU-132, a biological pharmaceutical therapy ("biologic") for metastatic triple-negative breast cancer ("mTNBC"). Id. ¶¶ 4, 68.

Pehl was Immunomedics' Chief Executive Officer ("CEO") from December 7, 2017 to February 25, 2019, and he also served on the company's Board of Directors during that time. Id. ¶ 28.

Garone was Immunomedics' Chief Financial Officer ("CFO") from the beginning of the Class Period through August 23, 2018, when he stepped down. Id. ¶ 34. Garone remained at the company as Vice President of Finance until his resignation from that position on December 24, 2018. Id.

Malik was Immunomedics' acting CFO from August 23, 2018 through the remainder of the Class Period. Id. ¶ 31. From August 2017 until his promotion to CFO, Malik was the company's Chief Business Officer. Id.

Rosenberg was Immunomedics' Chief Technology Officer ("CTO") throughout the Class Period. Id. ¶ 37. Prior to becoming CTO in January 2018, Rosenberg was a consultant with the company for nine months whose responsibilities included "building an outstanding team and preparing for commercial launch [of IMMU-132]." Id.

Pehl, Garone, and Malik were responsible for complying with Immunomedics' Code of Ethics for the CEO and Senior Financial Officers. See id. ¶¶ 29, 32, 35. Pehl, Garone, and Malik were also subject to Immunomedics' External Communications Policy, which provided that the CEO, CFO, and Head of Investor Relations were the only persons authorized by Immunomedics "to speak on its behalf to the public." Id. Rosenberg's actions were also governed by the External Communications Policy and he "could not speak on behalf of [Immunomedics] without the prior approval of the Company Spokespersons (i.e., the current CEO, CFO and Head of Investor Relations . . .)." Id. ¶ 38.

Aghazadeh has been a member of Immunomedics' Board of Directors since March 2017. Id. ¶ 40. During the Class Period, he was the Executive Chairman of the Board. Id. ¶ 40.

Canute has been a member of Immunomedics' Board of Directors since March 2017. Id. ¶ 42. During the Class Period, Canute served on the Board's Executive Committee, Audit Committee, Compensation Committee, Governance and Nominating Committee, and Research and Development Committee. Id.

Hutt has been a member of Immunomedics' Board of Directors since March 2017. Id. ¶ 44. Throughout the Class Period, Hutt served on the Board's Executive Committee, Compensation Committee, and Governance and Nominating Committee. Id.

Islam has been a member of Immunomedics' Board of Directors since March 2017. Id. ¶ 46. Throughout the Class Period, Islam served on the Board's Executive Committee, Audit Committee, Compensation Committee, Governance and Nominating Committee, and Research and Development Committee. Id.

Aghazadeh, Canute, Hutt, and Islam were installed on the Board following a "proxy battle" led by venBio Select Advisor LLC ("venBio"), described in more detail infra. Id. ¶ 6.

The Individual Defendants were promoted or hired to "deliver IMMU-132 to the market." Id. ¶ 67.

B. The FDA Approval Process

FDA approval for biologics like IMMU-132 "includes completion of preclinical laboratory tests and animal studies, performance of clinical trials in humans, submission of a [biologic license application ('BLA')], and FDA review and approval of the [BLA]." Id. ¶ 69. The FDA's review involves "mak[ing] a determination that the manufacturing process and facilities meet applicable regulations." Id. ¶¶ 69-70. When reviewing a BLA, the FDA "conducts . . . a pre-approval inspection of the applicant's manufacturing facilities" to ensure compliance with relevant regulations.[2] Id. ¶ 73.

As part of the manufacturing inspection, "a notice on FDA Form 483 may be issued if an inspector finds conditions at a manufacturing facility to be in violation of the Federal Food, Drug and Cosmetic Act, cGMP, or any other applicable regulations," and where an FDA inspector prepares a Form 483, "each observation is read and discussed with management at the inspection close-out meeting so that the company understands the significance of each observation." Id. ¶¶ 75-76. Following the inspection, the FDA also issues a written Establishment Inspection Report ("EIR"). Id. ¶ 77.

The "final step" in the FDA's BLA review is the issuance of either an approval letter or a Complete Response Letter ("CRL"). Id. ¶ 78. A CRL indicates "that the product is not ready for approval." Id.

C. IMMU-132's Approval Process, the Data Integrity Breach, the Follow-on Stock Offering, and Defendants' Public Representations

In February 2016, the FDA granted Breakthrough Therapy Designation to IMMU-132, which "provides for expedited FDA review." Id. ¶ 5.

In February 2017, Immunomedics "announced that it had entered into a $2 billion licensing agreement with Seattle Genetics, Inc. ('Seattle Genetics')," pursuant to which Seattle Genetics would "conduct[] a Phase 3 clinical trial for IMMU-132 . . . submit[] the [BLA] to the FDA for review . . . [and] be solely responsible for manufacturing and commercializing IMMU-132." Id. ¶ 6. Immunomedics' largest shareholder, venBio, objected to this licensing agreement and led a "proxy battle" that resulted in "venBio representatives . . . gaining four seats on the Immunomedics Board of Directors and ousting the Company's top executives, including its Chief Executive Officer." Id. On May 5, 2017, Immunomedics announced that Seattle Genetics had agreed to terminate the licensing agreement. Id. ¶ 65.

In Spring 2017, Immunomedics' new Board of Directors, which included Aghazadeh, Canute, Hutt, and Islam, "informed investors that they—unlike Immunomedics' prior

[2] The FDA refers to these regulations as current Good Manufacturing Practices ("cGMP"). Consol. Compl. ¶ 73. Immunomedics "emphasized the importance of complying with cGMP" in its Securities & Exchange Commission ("SEC") filings. Id. ¶ 74 (including excerpts from Immunomedics' Form 10-K annual report).

management—possess[ed] the requisite expertise to establish the necessary manufacturing infrastructure for IMMU-132 . . . [to] obtain[] FDA approval and launch[] the drug in the United States during 2018." Id. ¶ 7.

On January 31, 2018, Defendants discovered that their Morris Plains, New Jersey manufacturing plant "suffered from a serious data integrity breach," which involved "[Immunomedics] personnel deliberately manipulating bioburden samples, deliberately misrepresenting test procedures in batch records and intentionally backdating batch records" (the "Data Integrity Breach" or the "Breach"). Id. ¶ 9. Pehl and the Immunomedics Board of Directors were informed of the Data Integrity Breach "in the days immediately following" the Breach. Id. ¶ 79; see also id. Ex. A. If Immunomedics did not remedy the Data Integrity Breach, it would jeopardize FDA approval of the IMMU-132 BLA. Id. ¶ 9.

Because Immunomedics had previously informed investors that "it would be filing the IMMU-132 BLA with the FDA in March 2018," on February 8, 2018, Immunomedics "told the investing public that it was pushing its BLA filing date out by two months." Id. ¶ 80. This public disclosure did not contain information regarding the Data Integrity Breach. Id.; see also id. ¶¶ 93 (including excerpt of press release and Form 8-K signed by Garone and filed with the SEC), 94-96 (describing statements Pehl and Rosenberg made with financial analysts on a February 8, 2018 conference call regarding Immunomedics' quarterly financial results and the status of the IMMU-132 BLA).

After the market closed on February 8, 2018, Immunomedics filed its Form 10-Q with the SEC for the second quarter of fiscal year 2018 ("2Q18"), which included the following risk disclosure: "Our Information Systems may be subject to interruption or damage from a variety of causes, including power outages, computer and communications failures, system capacity constraints, catastrophic events (such as fires, tornadoes and other natural disasters), cyber risks, computer viruses and security breaches."[3] Id. ¶ 97 (the "Risk Disclosure"). On May 9, 2018, Immunomedics filed its Form 10-Q for the third quarter of fiscal year 2018 ("3Q18"), which contained the Risk Disclosure. Id. ¶ 100. That day the company held a conference call with financial analysts and investors to discuss its financial results, wherein Pehl did not raise the Data Integrity Breach or Immunomedics' response. Id. ¶ 99.

On May 21, 2018, Immunomedics submitted the BLA for IMMU-132. Id. ¶ 81.

On June 11, 2018, Immunomedics filed a Form S-3ASR Registration Statement (the "Registration Statement") with the SEC "for a follow-on offering of securities, including common stock," which was signed by Pehl, Garone, Aghazakeh, Canute, Hutt, and Islam, and which contained the Risk Disclosure. Id. ¶ 102. Three days later, Immunomedics filed a Form 424B5 Prospectus (the "Prospectus") for the offering of "at least 11.5 million shares of common stock at a price of $24.00 per share," which also included the Risk Disclosure. Id. ¶ 103. On June 15, 2018, Immunomedics announced it had sold over 11.5 million shares of stock "for net proceeds of $300 million" from this follow-on stock offering. Id. ¶¶ 15, 104. "[M]arket participants were

[3] The Risk Disclosure also explained that this risk "could have a material adverse effect on our business, financial condition and results of operations. Our clinical trials information . . . is part of our Information Systems and is therefore subject to all of the risks set forth above." Consol. Compl. ¶ 97.

keenly focused on the regulatory pathway of IMMU-132, including the FDA's BLA pre-approval inspection of [Immunomedics'] Morris Plains manufacturing facility." Id. ¶ 56.

Between August 6 and August 14, 2018, the FDA conducted the pre-approval manufacturing facility inspection, and on August 14, 2018, it issued a Form 483 to Pehl and Immunomedics, logging thirteen issues, including two related to the Data Integrity Breach (the "Form 483"). Id. ¶ 82; see also id. Exs. B-C. The FDA "could make no assessment whether the Data Integrity Breach had been remediated because documentation necessary to make that assessment was deliberately withheld by Defendants pursuant to attorney-client privilege." Id. ¶ 82.

On August 23, 2018, Immunomedics filed its 2018 Form 10-K with the SEC which included the Risk Disclosure and which also "contained risk disclosure language concerning the Company's potential receipt of a Form 483."[4] Id. ¶ 106 (emphasis in original).

The FDA subsequently issued an EIR which "contained a detailed narrative" of the August inspection, including observations related to the Data Integrity Breach. Id. ¶¶ 84-88. In particular, the EIR noted that Rosenberg "failed to disclose the issue related to the integrity test procedures discovered by Immunomedics in January 2018 until the inspector directly asked about it" and that "the scope of the Data Integrity Breach was much broader than what had initially been disclosed to the FDA in Immunomedics' early 2018 letter to the agency." Id. ¶¶ 86-88.

On September 4, 2018, Immunomedics sent the FDA a response to the Form 483 which explained that the company had implemented several changes in response to the Data Integrity Breach. Id. ¶ 83.

On November 7, 2018, Immunomedics filed its Form 10-Q for the first quarter of fiscal year 2019 ("1Q19"), which contained the Risk Disclosure,[5] and held an earnings call wherein Pehl and Malik disclosed neither the Data Integrity Breach nor the company's receipt of the Form 483. Id. ¶¶ 108-10.

On December 17, 2018, "FDANews published a brief article stating that [Immunomedics'] Morris Plains manufacturing facility had been cited by the FDA for a number of violations due to [the Data Integrity Breach]," which led to Immunomedics' share price falling 5% that day. Id. ¶¶ 120-21. On December 20, 2018, an equity analyst issued a "report disclosing in further detail the contents of the August 14, 2018 Form 483 . . . [raising] fears that the FDA would not approve the IMMU-132 BLA." Id. ¶¶ 112, 122. That day, Immunomedics' share price fell to $12.96 from its prior close of $17.46. Id. ¶ 123.

Following these publications, Pehl and Malik made additional, allegedly misleading statements "through friendly sell-side analysts to assure investors that their concerns were overblown." Id. ¶¶ 113-16 (including quotations from analyst reports from Guggenheim, Morgan Stanley, Wells Fargo, and Piper Jaffray which reflected conversations with Immunomedics' senior management including Pehl and Malik).

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[4] Pehl, Garone, Aghazakeh, Canute, Hutt, and Islam signed the 2018 Form 10-K. Consol. Compl. ¶ 106.

[5] This filing also included an additional risk statement: "Our employees and our independent contractors . . . may engage in misconduct or fail to comply with certain regulatory standards and requirements, which could expose us to liability and adversely affect our reputation." Consol. Compl. ¶ 110.

After the market closed on January 17, 2019, Immunomedics "announced it had received a CRL from the FDA, which rejected the approval of IMMU-132." Id. ¶ 124. On January 18, 2018, Immunomedics' share price fell from $18.09 to $13.31. Id. ¶ 126.

Plaintiffs allege that "[b]ut for Defendants' deliberate decision to withhold information related to the Data Integrity Breach, Immunomedics' Class Period stock price would have been significantly lower, and the Company would not have been able to obtain the $300 million [stock offering] on the same terms." Id. ¶ 130.

Plaintiffs filed the Consolidated Complaint on November 18, 2019, bringing two counts against Defendants: (1) violations of Section 10(b) of the Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78j(b), and Rule 10b-5 thereunder, 17 C.F.R. § 240.10b-5, which prohibit fraud in connection with the purchase or sale of any security, see Consol. Compl. ¶¶ 139-44 ("Count I"); and (2) violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t, against the Individual Defendants as control persons of Immunomedics, Consol. Compl. ¶¶ 145-48 ("Count II").

II. LEGAL STANDARD

In considering a Rule 12(b)(6) motion to dismiss, the court accepts as true all of the facts in the complaint and draws all reasonable inferences in favor of the plaintiff. Phillips v. Cty. of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008). Moreover, dismissal is inappropriate even where "it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits." Id. However, the facts alleged must be "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). That is, the allegations in the complaint "must be enough to raise a right to relief above the speculative level." Id. Accordingly, a complaint will survive a motion to dismiss if it provides a sufficient factual basis such that it states a facially plausible claim for relief. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

Additionally, Plaintiffs must meet the heightened pleading requirements under Rule 9(b) and the Private Securities Litigation Reform Act ("PSLRA") because their Exchange Act claims sound in fraud. See City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 168 (3d Cir. 2014). To allege fraud under Rule 9(b), "a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). At a minimum, "plaintiffs [must] support their allegations of securities fraud with all of the essential factual background that would accompany the first paragraph of a newspaper story—that is, the who, what, when, where and how of the events at issue." In re Alpharma Inc. Sec. Litig., 372 F.3d 137, 147 (3d Cir. 2004) (internal quotation marks and citation omitted).

III. ANALYSIS

A. Section 10(b) Claims

To state a claim under Section 10(b) of the Exchange Act, a plaintiff must plead, consistent with the PSLRA's heightened standards, "(1) a material misrepresentation or omission, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation or omission, (5) economic loss, and (6) loss causation." City of Edinburgh Council, 754 F.3d at 167; see also Padgett v. RiT Techs. Ltd.,

No. 16-4579, 2019 WL 913154, at *5 (D.N.J. Feb. 22, 2019). Defendants argue that the Court should dismiss Count I because Plaintiffs have failed to satisfy the first two elements. See Def. Br. at 11-32, ECF No. 48.1. The Court addresses each in turn.

1. Material Misrepresentations or Omissions

Defendants first argue that Plaintiffs have not pled any actionable misstatements or omissions. Id. at 11-23. The Court disagrees.

A misstatement or omission is material "if there is a substantial likelihood that a reasonable shareholder would consider it important in making an investment decision." In re Constar Int'l Inc. Sec. Litig., 585 F.3d 774, 783 (3d Cir. 2009) (internal quotation marks omitted). "The ultimate issue of materiality should not be decided as a matter of law unless 'the disclosures or omissions are so clearly unimportant that reasonable minds could not differ.'" Carmignac Gestion, S.A. v. Perrigo Co. PLC, No. 17-10467, 2019 WL 3451523, at *9 (D.N.J. July 31, 2019) (quoting In re Galena Biopharma, Inc. Sec. Litig., 336 F. Supp. 3d 378, 390 (D.N.J. 2018)); see also Ieradi v. Mylan Laboratories, Inc., 230 F.3d 594, 599 (3d Cir. 2000) ("[W]here there is room for differing opinions on the issue of materiality, the question should be left for jury determination.") (citation omitted).

Here, Plaintiffs allege that Defendants made numerous statements and omissions which a reasonable shareholder could consider material. For example, on February 8, 2018, Pehl indicated in a press release that he was "very pleased with the overall status and quality and c[ould] confirm that all critical work streams [for FDA approval], including . . . manufacturing validation runs, [were] yielding positive results." Consol. Compl. ¶¶ 93-94. That same day, Rosenberg represented that IMMU-132's FDA review would be "very much sort of a check-the-box exercise." Id. ¶¶ 95-96. At this time, Pehl and Rosenberg were aware of the Data Integrity Breach and that it could seriously jeopardize IMMU-132's FDA approval. See id. ¶¶ 9-10, 86, 105; see also id. Ex. A at 2 ("[I]n the days immediately following [the Data Integrity Breach] the Company escalated the matter up to the CEO, engaged counsel to investigate the matter with the active and essential support of the Quality Unit, briefed board leadership, and began evaluating potential product and patient impact.").

Because "market participants were keenly focused on the regulatory pathway of IMMU-132," id. ¶ 56, Pehl and Rosenberg's failure to disclose the Data Integrity Breach is sufficient to maintain a Section 10(b) claim at this stage. See, e.g., Williams v. Globus Med., Inc., 869 F.3d 235, 241 (3d Cir. 2017) (finding that "[o]nce a company has chosen to speak on an issue—even an issue it had no independent obligation to address—it cannot omit material facts related to that issue so as to make its disclosure misleading"); Curran v. Freshpet, Inc., No. 16-2263, 2018 WL 394878, at *4-5 (D.N.J. Jan. 12, 2018) (denying motion to dismiss where defendants' statements on earning calls were materially misleading because "[d]efendants knew . . . that [the company] was facing substantial obstacles that would impede [its] growth . . . [including] alleged manufacturing problems"). Additionally, a reasonable shareholder could consider the 2Q18, 3Q18, and 1Q19 Form 10-Q filings, the Registration Statement, the Prospectus, and the 2018 Form 10-K material misrepresentations because they contained the Risk Disclosure, which framed a data breach as a potential risk when such a risk had already materialized. See

Consol. Compl. ¶¶ 97-100, 102-03, 106-10; Williams, 869 F.3d at 242 (3d Cir. 2017) ("[A] company may be liable under Section 10(b) for misleading investors when it describes as hypothetical a risk that has already come to fruition.").[6]

Because a reasonable shareholder could consider the omitted information about the Data Integrity Breach and the Form 483 to be important when making an investment decision, Plaintiffs have adequately alleged the first element of a Section 10(b) claim. City of Edinburgh Council, 754 F.3d at 167.

2. Scienter

Defendants next argue that Plaintiffs have not adequately alleged scienter. See Def. Br. at 24-32. The Court disagrees.

To satisfy the scienter requirement, Plaintiffs must "allege facts giving rise to a strong inference of either reckless or conscious behavior." Institutional Invs. Grp. v. Avaya, Inc., 564 F.3d 242, 267 (3d Cir. 2009) (internal quotation marks and citations omitted). The inference "need not be irrefutable, i.e., of the 'smoking-gun' genre," but the Court "must consider the complaint in its entirety" and "must take into account plausible opposing inferences." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322-24 (2007).

"[W]hen the alleged fraud is based on non-disclosure of facts, evidence that the defendants had actual knowledge of the facts is sufficient to show scienter." In re Great Atl. & Pac. Tea Co., Inc. Sec. Litig., 103 F. App'x 465, 469 (3d Cir. 2004). Here, Plaintiffs allege that each Defendant knew about the seriousness of the Data Integrity Breach, yet issued public statements that failed to disclose that event and its potential impact on the FDA approval process. See Consol. Compl. ¶¶ 9-10 (explaining that Defendants "acknowledged that they concluded the Data Integrity Breach was of the 'utmost concern' to them" but still "withheld from the FDA . . . facts underlying the scope of the Data Integrity Breach and whether it was ever remediated"), 79 (explaining that the Individual Defendants were notified of the Data Integrity Breach "in the days immediately following" the event), 93-100 (describing statements made by Pehl and Rosenberg to investors and market analysts in February and May 2018 which did not disclose the Data Integrity Breach).[7]

The Consolidated Complaint alleges this non-disclosure continued into the fall and winter of 2018 despite Defendants receiving the Form 483 on August 14, 2018. See id. ¶¶ 17 (describing August 14, 2018 "pre-approval inspection close-out meeting" between FDA inspectors and Immunomedics' "senior executives," including Pehl, where FDA inspectors stated their findings), 82-92 (noting that the FDA provided the Form 483 to the Individual Defendants, and explaining that it indicated Rosenberg "refused to honor the FDA's repeated requests for documentation supporting this verbal claim [that the Data Integrity Breach had been remediated]" and that "the scope of the Data Integrity Breach was much broader than what had initially been disclosed to the

[6] The 1Q19 Form 10-Q and 2018 Form 10-K also referred to receiving a Form 483 from the FDA as a hypothetical issue even though Immunomedics had, in fact, already received one. See Consol. Compl. ¶¶ 106, 108-10.

[7] Additionally, Immunomedics' SEC filings for the Class Period, ratified on at least one occasion by each Individual Defendant except Rosenberg, contained only the Risk Disclosure and failed to identify the Data Integrity Breach or receipt of the Form 483. See Consol. Compl. ¶¶ 100-09 (explaining that Pehl and Garone signed the 3Q18 Form 10-Q; Pehl, Garone, Aghazakeh, Canute, Hutt and Islam signed the Registration Statement; Pehl, Garone, Aghazakeh, Canute, Hutt and Islam signed the 2018 Form 10-K; and Pehl and Malik signed the 1Q19 Form 10-Q).

FDA in Immunomedics' early 2018 letter to the agency"), 105 (explaining the scope of the Data Integrity Breach and its impact on the IMMU-132 approval process), 127-30 (alleging that there was significant pressure on the Individual Defendants to successfully commercialize IMMU-132 in 2018); see also id. Exs. B-C. Reading the Consolidated Complaint as a whole, "Plaintiffs properly allege scienter based on Defendants' conscious decision to omit presently known facts," particularly when presented with "information about difficulties facing" IMMU-132's FDA approval. See Curran, 2018 WL 394878, at *5.

Additionally, Immunomedics had a "long history of operating losses" such that "the financing from the June 2018 [stock] offering" was critical to the company's "ultimate commercialization of IMMU-132." Consol. Compl. ¶ 130. The Data Integrity Breach and Form 483 issues therefore concerned "core matters of central importance to a company." Carmignac Gestion, 2019 WL 3451523, at *16. Material misrepresentations regarding such "core matters . . . may support an inference of scienter when accompanied by some additional allegation of specific information conveyed to management and related to the fraud." Id. (citing Martin v. GNC Holdings, Inc., 757 F. App'x 151, 155 (3d Cir. 2018)) (internal quotation marks omitted). Those additional allegations are present here. For example, Plaintiffs explain that "in the days immediately following [the Data Integrity Breach] the Company escalated the matter up to the CEO, engaged counsel to investigate the matter with the active and essential support of the Quality Unit, briefed [Board of Directors] leadership, and began evaluating potential product and patient impact." Consol. Compl., Ex. A at 2. Similarly, Plaintiffs allege that a June 4, 2018 Immunomedics press release quoted Pehl as stating, "I think we did really, really [well] with the additional time that we gave ourselves due to feedback of FDA who wanted to have some additional . . . information . . . [and] to make sure [the IMMU-132 BLA] c[ame] in the highest possible quality." Id. ¶ 101. The next week, Defendants filed the Registration Statement and Prospectus for the $300 million follow-on stock offering which contained the Risk Disclosure that "failed to disclose the Data Integrity Breach." Id. ¶¶ 102-05; see In re Enzymotec Sec. Litig., No. 14-5556, 2015 WL 8784065, at *19 (D.N.J. Dec. 15, 2015) ("Crucially, Lead Plaintiffs specifically tie together the timing of the[] [follow-on stock offering] with the core of the alleged misrepresentations[.]"); see also Consol. Compl. ¶¶ 106-11 (describing Defendants' public statements and SEC filings between August 23 and November 13, 2018 which did not contain information regarding the Data Integrity Breach, the Form 483, or the EIR).

Accepting these allegations as true, the Court concludes that Plaintiffs have adequately alleged scienter and have therefore stated a claim for securities fraud under Section 10(b). Defendants' Motion is denied as to Count I.

B. Section 20(a) Claims

Defendants argue that Plaintiffs have not stated a claim under Section 20(a) of the Exchange Act. See Def. Br. at 32-34. The Court disagrees.

Section 20(a) "creates a cause of action against individuals who exercise control over a controlled person, including a corporation, that has committed a violation of Section 10(b)." Enzymotec Sec. Litig., 2015 WL 8784065, at *19 (citing 15 U.S.C. § 78t(a) and In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 284 (3d Cir. 2006)). To state a claim under Section 20(a), Plaintiff must demonstrate a violation of the Exchange Act, that the Individual Defendants

were controlling persons of the corporation, and that the Individual Defendants were "culpable participant[s] in the fraud." Supreme Specialties, 438 F.3d at 284 n.16.

Here, Plaintiffs have adequately pled that the Individual Defendants were controlling persons at Immunomedics by virtue of their positions in senior management and on the Board of Directors, and that the Individual Defendants participated in the alleged fraud. See Consol. Compl. ¶¶ 28-47 (describing the Individual Defendants' roles and their allegedly false statements or omissions). "Because the Court finds that Plaintiffs have sufficiently pled [Section 10] Exchange Act claims, it cannot dismiss the derivative Section 20 claim[s] against individual [d]efendants at this time." Curran, 2018 WL 394878, at *7; Enzymotec Sec. Litig., 2015 WL 8784065, at *19-20 (same). Accordingly, Defendants' Motion is denied as to Count II.

IV. CONCLUSION

For the reasons stated above, Defendants' Motion to Dismiss, ECF No. 48, is **DENIED**.

SO ORDERED.

/s Madeline Cox Arleo
MADELINE COX ARLEO
UNITED STATES DISTRICT JUDGE